REMARKS

In the present Amendment, independent claims 19, 29 and 31 have been substantively amended, and new evidence is provided in the Appendix. Consequently, the present amendment is expected to require further consideration and/or search. For these reasons, the amendment is being filed with a Request for Continued Examination.

Status of the Claims

Claims 19, 29 and 31 have been amended to recite an amylose content between 30 and 40% dry/dry as described on page 14, lines 30-35 of the specification.

Claim 24 is amended to further limit claim 19.

In light of the amendment to claim 19, claims 20 and 22, which no longer further limit claim 19, are cancelled without prejudice.

Claim 30 and claims 41-43, which depended from claim 30, are also cancelled without prejudice, as claim 30 was a duplicate claim of claim 29.

Claims 19, 21, 24-29, 31-40 and 44-47 remain pending.

Claim Rejections-35 USC §103

Claims 19-22, 24-27, 29, 30, 32-36 and 40-43 stand rejected under U.S.C. § 103(a) as being unpatentable over LYDZINSKI et al. U.S. 2003/0099692 (LYDZINSKI) in view of

MCCREADY et al. Anal. Chem., 1950 (MCCREADY). This rejection is respectfully traversed for the reasons that follow.

LYDZINKSKI was offered for teaching a composition that may include hydroxypropylated legume starch, including a pea starch.

MCCREADY was offered for teaching types of peas.

The maintained rejection is based on the following conclusion:

> "[O]ne of ordinary skill would be motivated to use various forms of pea starch, and to at least try the pea starches of McCready, including the smooth pea starch."

However, MCCREADY fails to indicate <u>any preference</u> for <u>smooth</u> pea starch. Indeed, of the eight peas and pea starch varieties disclosed by MCCREADY in Table III, only three are smooth. MCCREADY indicates in the paragraph immediately following the table that the smooth pea starch evaluated contained 36% amylose, and the wrinkled pea starch contained 70% amylose. Thus, the majority of the pea starches listed by MCCREADY have an amylose content greater than the claimed between 30 and 40% amylose content.

Moreover, the wrinkled pea starch containing 70% amylose disclosed by MCCREADY seems to be more consistent with the exemplified compositions of LYDZINSKI than smooth pea starch. LYDZINSKI solely illustrates the use of modified high amylose, i.e., 70%, or waxy corn starches, i.e., with no more than 5% amylose, and native tapioca starch (See [0039]-[0045]). While

LYDZINSKI broadly describes starch from a source such as "cereals, tubers, roots, legumes and fruits", which may be subjected to any physical, chemical, and/or enzymatic modifications (see [0011] to [0013]), including hydroxypropylation, there is no suggestion that a starch having a 30-40% amylose content, such as smooth pea starch, is preferred.

Indeed, the only mention of pea starch by LYDZINSKI is relative to the native starch source:

> "The native source can be corn, pea, potato, sweet potato, banana, barley, wheat, rice, sago, amaranth, tapioca, arrowroot, canna, sorghum, and waxy or high amylose varieties thereof. As used herein, the term "waxy" is intended to include a starch containing at least about 95% by weight amylopectin and the term "high amylose" is intended to include a starch containing at least about 40% by weight amylose."

Thus, neither LYDZINKSI nor MCCREADY show a preference for selecting any starch having an amylose content of 30 to 40% amylose content.

Even if one would have randomly selected smooth pea starch from MCCREADY, there would have been no expectation of the superior results of the claimed "film-forming starchy composition for the film-coating of solid forms or for the preparation of films", as demonstrated in Table 3 of the present specification.

MCCREADY mentions nothing of film properties, and LYDZINSKI, as evidenced by the examples, failed to recognize the superior film properties achieved by a pea starch with an amylose content of between 30 and 40%.

Table 3 rates the film/coating properties for various prepared starch compositions on a scale (see page 18, line 12 of the specification) from "+++"(best) to "0"(worst). The compositions include those disclosed by LYDZINSKI, such as waxy starch, high amylose starch and modifications that include hydroxypropylation. These comparative starches include amylose contents greater and less than that claimed, as well as different modifications of the starch. The amylose contents greater than the claimed range and the different types of modification are all disclosed by LYDZINSKI.

Responsive to the Official Action, the rating system used (0, +, ++, and +++), and the agglomeration property, are further explained in the newly executed Declaration provided in the Appendix along with the Annexes 1, 2, and 3.

Annex 1, as explained in the declaration, provides the quantitative correlation or qualitative correlation from "0" to "+++" for each characteristic.

Annex 2 shows tablets that were rated as "+++" (Figures 1 and 2) and tablets that were rated as "0" (Figures 3 and 4) for the physical aspects of the coating. A blue color was used with the coating so that the quality of the coating, e.g., in terms of homogeneity, could be determined. That is, as explained in the declaration, Figures 1 and 2 are a homogeneous blue color, whereas Figures 3 and 4 are non-homogeneous with white, pale blue and dark blue areas. As the USPTO does not generally review

colored Figures, Annex 2 further includes Figures 1-4 labeled as "grayscale", which also illustrates the difference between the homogeneous shade of the tablets of Figures 1 and 2 and the non-homogeneous shade of the tablets of Figures 3 and 4, which include white areas, pale shades, and darker shades.

Annex 3 includes the procedure for determining the amylose content.

Thus, the results demonstrated by the claimed composition having amylose content of between 30 and 40% by dry weight of starch present in a composition and at least one hydroxypropylated pea starch, are unexpectedly superior in view of LYDZINSKI and MCCREADY. As discussed above, MCCREADY mentions nothing of film properties and fails to express a preference for smooth pea starch, and LYDZINSKI, as evidenced by the examples of LYDZINSKI, failed to recognize the superior film properties achieved by a pea starch with an amylose content of between 30 and 40%.

Therefore, as the proposed combination fails to suggest the claimed invention or the unexpected results, the claims are not rendered obvious. Withdrawal of the rejection is respectfully requested.

Claims 31 and 44-46 stand rejected under U.S.C. § 103(a) as being unpatentable over LYDZINSKI in view of MCCREADY, and

further in view of FUERTES US 6,469,161 (FUERTES). This rejection is respectfully traversed for the reasons that follow.

For the reasons discussed above, LYDZINSKI and MCCREADY fail to render obvious a composition having amylose content of between 30 and 40% by dry weight of starch present in a composition and at least one pea starch.

FUERTES relates to a chemical fluidification process for a starchy material. However, FUERTES is completely silent about specific film-forming compositions, in particular composition comprising hydroxypropylated or acetylated legume starch and having a certain amylose content.

Consequently, FUERTES does not remedy the shortcomings of LYDZINSKI and MCCREADY for reference purposes.

Therefore, the claimed invention is not rendered obvious by the combination of LYDZINSKI MCREADY and FUERTES, and withdrawal of the rejection is respectfully requested.

Claims 19, 28, 37-39 and 47 stand rejected under U.S.C. § 103(a) as being unpatentable over HAASMAA US 2002 0032254 (HAASMAA) in view of MCCREADY and further in view of KIM US 6,123,963(KIM). This rejection is respectfully traversed for the reasons that follow.

As stated previously, HAASMAA does not provide any guidance for the selection of a starch having an amylose content between 30 and 40%.

HAASMAA simply provides an exhaustive list of starch sources which includes barley, potato, wheat, oat, pea, corn, tapioca, sago, rice, or a similar rubber-bearing or rain plant. HAASMA discloses that there may be anywhere from 0% to 100% amylose content ([0026]). Indeed, barley starches, or at least cereal starches, appear to be preferred as the Examples only utilize barley starches. Thus, HAASMAA provides no guidance in specifically choosing an amylose content between 30 and 40%.

As noted above, MCCREADY fails to indicate any preference for smooth pea starch. Indeed, of the eight peas and pea starch varieties disclosed by MCCREADY in Table III, only three are smooth. MCCREADY indicates in the paragraph immediately following the table that the smooth pea starch evaluated contained 36% amylose, and the wrinkled pea starch contained 70% amylose. Thus, the majority of the pea starches listed by MCCREADY have an amylose content greater than the claimed between 30 and 40% amylose content.

Neither LEUSNER nor KIM provides any guidance for selecting a starch with an amylose content of between 30 and 40%. LEUSNER was cited for teaching the hydroxypropylation of starch, but LEUSNER notes that hydroxypropylation decreases the tendency towards retrogradation of the starches (column 1, lines 23-24) KIM was offered for teaching conventional methods for coating tablets, granules, pellets, crystals, and capsules include coating in a fluidized bed and dip-coating (column 6, lines 58-65).

Thus, the proposed combination of documents offers no suggestion or motivation for selecting a starch with an amylose content of between 30 and 40%.

If one would have randomly selected smooth pea starch from MCCREADY, there would have been no expectation of the superior results of the claimed invention, as demonstrated in Table 3 of the present specification. MCCREADY mentions nothing of film properties, and HAASMAA, as evidenced by the barley or cereal-based, examples, failed to recognize the superior film properties achieved by a pea starch with an amylose content of between 30 and 40%.

As shown in Table 3, prepared starch compositions were rated for their film/coating properties on a scale (see page 18, line 12 of the specification) from "+++"(best) to "0"(worst). These ratings, and the agglomeration property, are explained in further detail in the newly executed Declaration along with the Annexes 1, 2, and 3 provided in the Appendix, in response to the Official Action.

Annex 1, as explained in the declaration, provides the quantitative correlation or qualitative correlation from "0" to "+++" for each characteristic.

Annex 2 shows tablets that were rated as "+++" (Figures 1 and 2) and tablets that were rated as "0" (Figures 3 and 4) for the physical aspects of the coating. A blue color was used with the coating so that the quality of the coating, e.g., in terms of

homogeneity, could be determined. That is, as explained in the declaration, Figures 1 and 2 are a homogeneous blue color, whereas Figures 3 and 4 are non-homogeneous with white, pale blue and dark blue areas. As the USPTO does not generally review colored Figures, Annex 2 further includes Figures 1-4 labeled as "grayscale", which also illustrates the difference between the homogeneous shade of the tablets of Figures 1 and 2 and the non-homogeneous shade of the tablets of Figures 3 and 4, which include white areas, pale shades, and darker shades.

Annex 3 includes the procedure for determining the amylose content.

Thus, as argued previously, Table 3 includes starches covered by the very broad disclosure of HAASMAA, but no explicit comparison is noted. The comparative examples of Table 3 include starches with high and low amylose content, which would be included in the great number of starch sources from 0% to 100 amylose content disclosed by HAASMAA. The amylose contents are either greater or less than the claimed invention.

The results demonstrate by the claimed composition having amylose content of between 30 and 40% by dry weight of starch present in a composition and at least one hydroxypropylated pea starch, are unexpectedly superior in view of HAASMAA, MCCREADY, LUESNER and KIM, fail to recognize the superior film properties achieved by a pea starch with an amylose content of between 30 and 40%.

Therefore, as the proposed combination fails to suggest the claimed invention or the unexpected results, the claims are not rendered obvious. Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims, the newly cited declaration and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following items:

- 37 CFR 1.132 Declaration of Philippe Lefevre
- Annex 1
- Annex 2 (color)
- Annex 2 (grayscale)
- Annex 3